REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 1-48 are pending in the present application. Claims 1-48 have been amended to more particularly point out and distinctly claim the present invention.

In the outstanding Official Action, claims 1, 4-13, 16-22, 25-31, 34-40, and 43-48 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is respectfully traversed.

In imposing the rejection, the Official Action alleges that the specification does not contain test results or experimental data showing that a predetermined amount of starch will, in fact, prevent dysglucaemia in a human not presently at risk of or predisposed to developing such a disorder. However, the Official Action fails to present any evidence to support this assertion.

As the Examiner is aware, as a matter of law, the expressed teaching of a patent specification cannot be controverted by speculation and unsupported assertions by the

Patent Office. As stated by the Court of Customs and Patent Appeals in the case of *In re Dinh-Nguyen Stenhagen*, 181 USPQ 46 (CCPA 1974):

> Any assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt so expressed.

181 USPQ at 47.

The Official Action fails to present any evidence that is in any way inconsistent with the teaching of the present specification, applicants believe that the Official Action fails to meet its burden in showing that the claimed invention is not enabled by the present disclosure.

In a non-diabetic person, the body regulates the blood glucose level very accurately under normal conditions, and the slow release of reducing sugars achieved by the method and composition would not be reflected in the blood glucose level. So, while a non-diabetic subject would benefit from exactly the same slow release, this would not be measurable under normal experimental conditions. It is evident that the beneficial effect is there, and it is expected that a test person would report sensations of well being, the absence of hunger, etc., again depending on the experimental conditions.

As to diabetic patients, the only difference between a diabetic and non-diabetic subject consists in that a diabetic patient produces insufficient levels of insulin. The conditions in the gastrointestinal tract, such as the enzymatic degradation, are identical. Consequently, a diabetic subject is in fact the ideal test person for showing the effect of the inventive method and composition. Applicants believe that a skilled person would understand the above reasoning and conclude that the results are equally applicable to healthy subjects.

A healthy person is naturally less prone to develop dysglucaemia, nevertheless that controlled, delayed enzymatic digestion of the starch and the consequently achieved substantially linear glucose release curve would naturally also benefit a healthy person.

Thus, it is believed that the present disclosure is enabling for the claimed invention.

Claims 2, 12-21, 23, 32, and 40-48 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants believe that the present amendment obviates this rejection.

The outstanding Official Action rejected claim 2 for reciting the term "including". However, claim 2 has been amended so that this term is no longer recited in the claim.

Claims 12-21 were rejected for reciting the phrase "such as". This term has also been removed from the claims and where appropriate, the claims have been amended to recite proper Markush groups.

Claims 40-48 were rejected for reciting the term "preferably". This term has been deleted from claims 40-48.

Applicants also note that claims 1-48 have been amended to recite "patient". Previously, the claims would alternatively state a patient or human. The claims have been amended so that they are directed to a patient so that consistent terminology is used.

Thus, in view of the above, it is believed that claims 1-48 are definite to one of ordinary skill in the art.

In the outstanding Official Action, claims 2, 23, 32, and 41 were rejected under 35 USC §103(a) as allegedly being unpatentable over KAUFMAN. Claims 3, 15, 24, 33, and 42 were then rejected under 35 USC §103(a) as allegedly being unpatentable over AXELSEN et al. These rejections are respectfully traversed.

Applicants believe that the cited publications fail to render obvious the claimed invention. While mentioning

"sustained release tablets, pills, lozenges and the like" (page 7, line 7), the document fails to disclose or suggest several features of the claimed invention. For example, the starch is in a granulated form so that the granulation delays the enzymatic degradation of the starch into reducing sugars.

It is also evident from the disclosure of KAUFMAN, that the preferred embodiment is a snack, wherein approximately 1/2 to 1/4 of the carbohydrate is substituted for uncooked cornstarch. The fact that the products reaching the market all comprise fats, protein, and simple sugars, further supports the conclusion that the present invention was not contemplated by KAUFMAN.

Indeed, the mere mentioning of tablets, pills, and lozenges does not render the present invention obvious. While the Official Action implies that the "art of formulation of tablets" would entail the binders mentioned in the present application, and render the invention obvious simply pressing a tablet from cornstarch would not result in the advantageous release profile achieved with the granulated starch according to the present invention.

The publications do not teach these recitations or the consequences of starch degradation and the beneficial effect on human subjects. As a result, applicants believe that it is neither described, suggested nor implied that specific

granulation would have the effects shown in the present application.

In citing AXELSEN et al. 6,316,427, the Official Action contends that this publication concerns a method for improving tolerance in a human suffering from impaired glucose tolerance (IGT), including both IGT and Diabetes Mellitus Type 2. However, the present application is concerned with Type 1 diabetes, that is insulin dependent diabetes mellitus (IDDM). There is no disclosure or suggestion that the results of AXELSEN et al. would be applicable to IDDM.

AXELSEN et al. set out to improve glucose tolerance in Type 2 diabetes. The goal is to keep the blood glucose levels down, as a sustained glucose production leads to accentuated hyperglycemia (col. 1, lines 24-28). It is neither disclosed nor suggested that the starch would need to be in granulated form, wherein the granulation delays the enzymatic degradation of the starch into reducing sugars, as specified in the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that the present application is now in condition for allowance, with claims 1-48, as presented. Allowance and passage to issue on that basis are accordingly respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R.§1.17.

Respectfully submitted,

YOUNG & THOMPSON

Philip A. DuBois, Reg. No. 50,696
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

PD/mjr